CharacTeristics of treAtment response to hIgh dose ICS/LABA vs. Medium or high dOse ICS/LABA + LAMA in patients with uncontRolled moderate to severe asthma on medium dose ICS/LABA - TAILOR study

First published: 19/11/2021

Last updated: 02/05/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/39040

EU PAS number

EUPAS39039

Study ID

39040

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] Italy
- [ ] Netherlands
- [ ] United Kingdom

Study description

In patients with uncontrolled moderate to severe asthma (i.e. GINA step 4), GINA recommends to either increase the dose of ICS to high dose ICS+LABA or to add a LAMA (tiotropium) on top of medium dose ICS+LABA. Although not recommended by GINA, it is likely that – in real life – there are also patients who get stepped-up to high dose ICS+LABA+LAMA. As of today, which patients respond best to which treatment option – in real life - is yet unknown. For this reason, we will conduct a retrospective cohort study, in patients with uncontrolled moderate to severe asthma (step 4) initiating one of the treatment options of GINA treatment step-up. Our study period is from 2010-2020 and we will use data from 4 databases from 4 European countries: the Netherlands (IPCI), Denmark (Aarhus), Italy (HSD) and UK (CPRD). The study population will consist of all patients with asthma, aged 18-65 years with at least 1 year of database history and active follow-up during the study. Within this cohort, patients with treatment step up from GINA step 4 (medium dose ICS/LABA) will be selected. The main objectives are as following: • Identify the main drivers of prescribing any of the three step-up treatment options • Identify patient features/characteristics associated with response to the specific treatment regimens In addition, we have the following secondary objectives: • To investigate differences in Health Care Resources utilisation in the year prior vs. year after treatment step-up (high dose ICS+LABA, medium dose ICS+LABA+LAMA, high dose ICS+LABA+LAMA) • To investigate differences in rescue medication use (SABA) and OCS use in the year prior vs year after treatment step-up • To study differences in treatment characteristics

(proportion of patients discontinuing treatment, switching (i.e. treatment step down)) after initiation of one of the 3 treatment options • To research the types of LAMAs being used

Study status

Ongoing

Research institutions and networks

Institutions

Erasmus Medical Centre Rotterdam

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

Denmark

First published: 20/07/2021

Last updated: 02/04/2024

Institution | Educational Institution | ENCePP partner

Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS), University of Oxford

United Kingdom

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility

Società Italiana di Medicina Generale e delle Cure Primarie (SIMG)

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Patient organisation/association

NDORMS Oxford - UK, SIMG Florence - Italy

Contact details

Study institution contact

Katia Verhamme

Study contact

k.verhamme@erasmusmc.nl

Primary lead investigator

Katia Verhamme

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 18/12/2020

Study start date

Actual: 01/01/2021

Data analysis start date

Planned: 01/03/2021

Date of interim report, if expected

Planned: 17/05/2021

Actual: 07/06/2021

Date of final study report

Planned: 15/06/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Chiesi

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

• identify the main drivers of prescribing any of the three step-up treatment options (high dose ICS/LABA, medium dose ICS/LABA+LAMA, high dose ICS/LABA+LAMA) • What patient features/characteristics are associated with response to the specific treatment regimen

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(R03D) OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

Medical condition to be studied

Asthma

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Estimated number of subjects

250000

Study design details

Outcomes

Severe asthma exacerbations and effect on spirometry data, Use of health care resources Treatment patterns

---

Data analysis plan

Descriptive statistical analyses, logistic regression and cluster analyses will be used. - Descriptive statistics to compare patients in the different treatment step-up cohorts (Main analysis 1) - Descriptive statistics to compare complete and partial responders and non-responders. - Identify determinants of response to each of the three step-up treatments by means of a logistic regression analysis. - Cluster analysis to describe phenotypes of patients responding to therapy - Analysis of change in healthcare resource utilisation (HCRU) and change in rescue medication by means of a Wilcoxon signed-rank test

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No